



This lot of product meets the accepted performance criteria recommended in the USP and ISO 11138-1.

Product Name: Spore Strips For use in Monitoring: Radiation Processes

Organism: *Bacillus pumilus* Derived from: ATCC® 27142

LOT BP1-1 **REF** SBP-06 Quantity: 100 strips
 2022-01-01 2025-01-01 (YYYY-MM-DD)

Performance Characteristics
Population: 2.0 x 10 ⁶ per 6 mm x 30 mm strip
<i>D</i> value
Cobalt ₆₀ : 1.5 kGy
The <i>D</i> value(s) were determined per the fraction negative method and are reproducible only when exposed and cultured under the exact conditions used to obtain results reported above. The user would not necessarily obtain the same results, therefore, should determine the suitability for their particular use.

Recovery

After exposure to the sterilization process, aseptically transfer each carrier to an individual tube containing 5-15 mL of Soybean Casein Digest Broth (SCDB). Incubate at 30° - 35°C for a minimum of 7 days or per validated reduced incubation time.

Examine tubes for growth, daily or as frequently as possible. Typical growth of *Bacillus pumilus* will be a lacy pellicle, cream-white in color.

Purity: Shall not contain any contamination that would adversely affect the performance or the stability characteristics of the biological indicator.

Storage and Shelf Life			
+15°C to +30°C	Room Temperature (15° - 30°C)		Keep away from sunlight
20% to 80%	20% to 80% Relative Humidity		Protect from heat, radioactive sources, and sterilizing agents
Shelf Life	36 Months from the date of manufacture		

Disposal: Autoclave, steam at 121°C for not less than 30 minutes or incinerate (standard microbial waste; non-pathogenic species).

QUALITY ASSURANCE APPROVAL

October 26, 2022
DATE